Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RICHARD L. LANDINGHAM

Appeal No. 2000-0920
Application No. 08/829,034

ON BRIEF

Before COHEN, STAAB, and McQUADE, *Administrative Patent Judges*.

STAAB, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on an appeal from the examiner's final rejection of claims 1-18 and 35-38. Claims 19-34, the only other claims pending in the application, have been withdrawn from consideration pursuant to 37 CFR § 1.142(b) as not being readable on the elected invention. The amendment filed subsequent to the final rejection on July 13, 1998 (Paper No. 8) has not been entered. See the advisory letter mailed July 24, 1998 (Paper No. 9).

Appellant's invention pertains to a cermet[1] (claims 1-10 and 35-38), and to a bone implant fabricated from an FDA approved cermet (claims 11-18). Claims 1 and 11 are representative and read as follows:

> 1. A cermet comprising a ceramic powder presintered into a porous ceramic matrix and infiltrated with a molten metal or metal alloy.
>
> 11. A bone implant fabricated from an FDA approved cermet comprising a ceramic powder presintered into a porous ceramic matrix and infiltrated with a molten metal or metal alloy.

The references applied in the final rejection are:

Holt et al. (Holt)	4,988,645	Jan. 29, 1991
Hirayama et al. (Hirayama)	5,128,146	Jul. 07, 1992

The following rejections are before us for review:

(a) claims 11-18, under 35 U.S.C. § 112, first paragraph, as being based on an original disclosure that fails to satisfy the enablement and description requirements found in that paragraph of the statute;

(b) claims 8, 36 and 38, under 35 U.S.C. § 112, second paragraph, "as being indefinite" (answer, page 4);

[1]Appellant's specification defines the term "cermet" as "a material comprising a metal or a metal alloy and a ceramic powder or a mixture of ceramic powders" (page 9, lines 32-33).

(c) claims 1-9, 11-17 and 35-37, under 35 U.S.C. § 102(b) as being anticipated by Holt or, in the alternative, under 35 U.S.C. § 103, as being obvious in view of Holt;

(d) claims 10, 18, 37 and 38, under 35 U.S.C. § 103 as being unpatentable over Holt in view of Hirayama.[2]

Reference is made to appellant's brief and supplemental brief (Paper Nos. 14 and 16) and to the examiner's answer (Paper No. 17) for the respective positions of appellant and the examiner regarding the merits of these rejections.

DISCUSSION

The 35 U.S.C. § 112, first paragraph, rejection.

The examiner's first reason for rejecting claims 11-18 under 35 U.S.C. § 112, first paragraph, is based on the enablement requirement found therein. According to the examiner (answer, paragraph bridging pages 3-4):

> The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention

[2]On page 6 of the answer, the examiner states that claims 10, 18, 37 and 38 are rejected under 35 U.S.C. § 103 "as being unpatentable over Holt et al[.] (US 4,988,645) as applied to claims 1-9 and 11-17 above, and further in view of Holt et al[.] (US 4,988,645) alone and Hirayama et al[.] (US 5,138,146)." Like appellant (brief, page 6; supplemental brief, page 3), we understand this rejection as being based on the combined teachings of Holt and Hirayama.

> commensurate in scope with these claims. Specifically, elemental calcium, iron, and nickel are clearly encompassed by the present claims as those materials with which the molten metal would be made. However, calcium metal evolves hydrogen when it contacts moisture or water and would cause harm to a living organism if implanted thereinto in a significant amount. Similarly, elemental iron would rust in the body and could lead to necrosis. Elemental nickel is a know [sic] carcinogen according to OSHA. For these reasons, the claims are considered so broad as to encompass inoperative embodiments.

The enablement requirement of the first paragraph of Section 112 "requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art." *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Although the examiner has hypothesized that cermets containing significant amounts of elemental calcium, iron, and nickel as the infiltrated metal would cause harm to a living organism, we think it is reasonably clear from appellant's disclosure[3] that claims 11-18 are directed to bone implants that do not encompass within their scope the utilization of infiltrated metal or metal alloy that would be incompatible with or harmful to the host organism. Pointing out, as the examiner has done here, that a claim is

[3]See, for example, page 26, line 34, through page 27, line 1, of the specification.

broad in that it reads on a broad range of embodiments is not sufficient. The mere fact that a claim embraces undisclosed or inoperative species or embodiments does not necessarily render it unduly broad. *Horton v. Stevens,* 7 USPQ2d 1245, 1247 (Bd. Pat. App. & Int. 1998), citing: *In re Dinh-Nguyen,* 492 F.2d 856, 858-59, 181 USPQ 46, 48 (CCPA 1974); *In re Bowen,* 492 F.2d 859, 863, 181 USPQ 48, 51-52 (CCPA 1974); *In re Smythe,* 480 F.2d 1376, 1385, 178 USPQ 279, 286 (CCPA 1973); *In re Kamal,* 398 F.2d 867, 872, 158 USPQ 320, 324 (CCPA 1968); *In re Sarett,* 327 F.2d 1005, 1019, 140 USPQ 474, 486 (CCPA 1964). Accordingly, we are not persuaded that the examiner has established a *prima facie* case of lack of enablement of claims 11-18.

The examiner's second reason for rejecting claims 11-18 under 35 U.S.C. § 112, first paragraph, is based on the description requirement found therein. The examiner states (answer, page 4):

> The amendment filed May 4, 1998 presented the new issue pertaining to the use of the limitation "FDA approved". It is not seen where this limitation has original support and the Examiner posits that it constitutes new matter with respect to the original specification and claims.

Appellant's specification states at page 27, lines 4-5, that alumina and titanium alloys, materials that may be used to make a

cermet suitable for bone replacement implants, "are . . . FDA approved implant materials." Assuming for the sake of argument that the recitation of "FDA approved implant materials" denotes materials approved by the United States Food and Drug Administration as being safe for implantation in the human body, it does not necessarily follow that a cermet made of FDA approved materials would itself likewise be "an FDA approved cermet," as now claimed. This circumstance, coupled with the fact that appellant has not pointed out where the disclosure as originally filed provides descriptive support for a bone implant "fabricated from an FDA approved cermet," leads us to conclude that the examiner's position in this regard is well taken. We therefore will sustain the examiner's rejection of claims 11-18 under 35 U.S.C. § 112, first paragraph, as being based on an original disclosure that does not comply with the written description requirement.

The 35 U.S.C. § 112, second paragraph, rejection.

The test for compliance with the second paragraph of Section 112 is "whether the claim language, when read by a person of ordinary skill in the art in light of the specification, describes the subject matter with sufficient precision that the bounds of the claimed subject matter are distinct." *In re*

Merat, 519 F.2d 1390, 1396, 186 USPQ 471, 476 (CCPA 1975). In other words, does a claim reasonably apprise those of skill in the art of its scope. *In re Warmerdam,* 33 F.3d 1354, 1361, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994).

The examiner contends that the use of the virgule "/" in claims 8 and 36, as in the term "porous ceramic matrix/molten metal interface" appearing in these claims, is not understood. We agree with appellant, however, that the meaning of the term in question would be reasonably clear to those of skill in the art, especially when read in light of the specification, which makes clear that the "interface" in question is the common boundary between the porous ceramic matrix and the infiltrated molten metal.

The examiner further contends that the use of the word "allow" in claim 38 renders the claim language "grammatically awkward" (answer, page 4). While we do not necessarily disagree with the examiner, we think the claim is definite in that the skilled artisan would recognize that the word intended is "alloy." In the event of further prosecution, this informality is deserving of correction.

In light of the above, the standing rejections under 35 U.S.C. § 112, second paragraph, will not be sustained.

The rejection under 35 U.S.C. § 102(b), or in the alternative, under 35 U.S.C. § 103, based on Holt.

Claim 1 is directed to a cermet comprising "a ceramic powder presintered into a porous ceramic matrix and infiltrated with a molten metal or metal alloy." The recitation that the porous ceramic matrix is formed by presintering a ceramic powder is a product-by-process limitation.

In assessing the process language of product claims during *ex parte* appeal, we take into account as limitations of the claimed subject matter, features imparted to the product by the process, and not the steps of the process itself; in other words, the determination of patentability is based upon the product itself, even though the claim may by defined by the process. Thus, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. *See Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 845-46, 23 USPQ2d 1481, 1490-91 (Fed. Cir. 1992) and *In re Thorpe*, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985).

Holt discloses a cermet made by a process that comprises reacting an aluminum powder compact in a high pressure nitrogen atmosphere utilizing a self-propagating high temperature

combustion synthesis to form a porous ceramic skeleton having interconnected pores. The resulting preform is then infiltrated with molten metal. See, for example, column 3, lines 20-45, and column 5, lines 46-61.

Appellant's specification (see pages 4-9) indicates that cermets made in accordance with the invention differ from prior art cermets in that cermets made in accordance with the invention have more evenly distributed porosity and more uniformly infiltrated metal than prior art cermets. This is achieved by, among other things, carefully selecting the ceramic starting material, ceramic material particle size, and metal or metal alloy to be infiltrated, so that the sintering temperature of the ceramic is above the melting temperature of the metal, thereby allowing the temperature of the molten infiltrating metal or metal alloy to be low enough during infiltration to preclude further sintering of the preformed ceramic matrix. See page 13, lines 9-24; page 15, line 33 through page 16, line 2; page 16, lines 17-22; page 16, lines 30-35; page 17, line 26 through page 18, line 14; and page 18, lines 22-28 of appellant's specification. However, claim 1 is very broad with respect to the process limitations by which the claimed product is made in that

it does not specify, for example, any particular ceramic starting material, ceramic material particle size, metal, or infiltration temperature.

Given the breadth of claim 1 and the disclosure of Holt that the cermet thereof comprises a porous ceramic skeleton having interconnected pores infiltrated with molten metal, we think the examiner has a reasonable basis for concluding that the cermet of Holt is either identical with or only slightly different than cermets encompassed by claim 1. Under such circumstances, a rejection based alternatively on either Section 102 or Section 103 of the statute, as the examiner has done here, is fair and acceptable. *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Appellant's summary argument on pages 5-6 of the brief and page 3 of the supplemental brief to the effect that Holt fails to teach the claimed cermet does not convince us that the examiner erred in rejecting claim 1. We therefore will sustain the standing rejection of claim 1 as being anticipated by Holt or, in the alternative, as being unpatentable over Holt.

Concerning claims 2-9 and 35-37, appellant has not presented arguments directed with any reasonable degree of specificity to these claims apart from claim 1. Therefore, the standing rejection of these claims as being anticipated by Holt, or in the

alternative, as being unpatentable over Holt, will also be sustained. *See In re Young*, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991); *In re Nielson*, 816 F.2d 1567, 1572, 2 USPQ2d 1525, 1528 (Fed. Cir. 1987); *In re Wood*, 582 F.2d 638, 642, 199 USPQ 137, 140 (CCPA 1978).

We now take up for consideration claims 11-17, which are directed to "[a] bone implant fabricated from an FDA approved cermet." As noted *supra* in our discussion of the standing 35 U.S.C. § 112, first paragraph, rejection of claims 11-18, we do not consider that appellant's original disclosure provides descriptive support for a cermet that is FDA approved. Nevertheless, it is improper to ignore this positive claim limitation in addressing the patentability of claim 11 in light of Holt.[4] For reasons stated *infra* in our new rejection entered under the provisions of 37 CFR § 1.196(b), we have encountered substantial difficulty in understanding precisely what is meant by the terminology "fabricated from an FDA approved cermet" as called for in claim 11. While we might speculate as to what is

[4]*See Ex parte Pearson,* 230 USPQ 711, 712 (1985), *aff'd. mem.,* 795 F.2d 1017 (Fed. Cir. 1986) ("Even though the above quoted expressions are held by us to introduce new matter into the claims, nevertheless, they cannot be ignored, but rather, must be considered and given weight when evaluating the claims so limited with regard to obviousness over art.").

meant by that claim language, our uncertainty provides us with no proper basis for making the comparison between that which is claimed and the prior art as we are obligated to do. Rejections based on prior art should not be based upon "considerable speculation as to [the] meaning of the terms employed and assumptions as to the scope of [the] claims." *In re Steele*, 305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962). When no reasonably definite meaning can be ascribed to certain terms in a claim, the subject matter does not become anticipated or obvious, but rather the claim becomes indefinite. *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Accordingly, we are constrained to reverse the examiner's rejections of appealed claims 11-17 as being anticipated by or unpatentable over the applied prior art. We hasten to add that this reversal is not based upon any evaluation of the merits thereof and does not preclude the examiner's advancement of a rejection predicated upon that art against a definite claim.

The rejection under 35 U.S.C. § 103 based on Holt in view of Hirayama.

Claims 10, 37 and 38 depend either directly or indirectly from claim 1 and further set forth details of the infiltrating metal alloy (claims 10 and 38) and ceramic powder used in making

the ceramic matrix (claim 37). In rejecting these claims, the examiner has taken the position (answer, page 6) that the additional features of these dependent claims do not patentably distinguish over the infiltrating metal alloys and ceramic powders disclosed in Holt.

Appellant does not specifically dispute the examiner's position in these respects. Instead, appellant argues (main brief, page 6; supplemental brief, pages 3-4) that the rejection of claims 10, 37 and 38 is improper because the applied references, taken alone or in combination, fail to teach or suggest the "infiltrating" and "presintering" features of base claim 1.

For the reasons set forth *supra* in our treatment of the standing anticipation/obviousness rejection of claim 1 based on Holt, appellant's argument that the product-by-process "presintering" feature of base claim 1 patentably distinguishes over Holt is not persuasive. Moreover, with respect to the "infiltrating" feature of base claim 1, Holt specifically states that the metal or metal alloy thereof is "infiltrated" into the preformed porous ceramic matrix. Accordingly, appellant's argument that the "infiltrating" feature of base claim 1 patentably distinguishes over Holt also is not persuasive. In

the absence of any other argument in favor of the patentability of claims 10, 37 and 38, the standing rejection thereof based on Holt in view of Hirayama will be sustained.

Claim 18 depends from claim 11 and therefore requires, among other things, that the bone implant be fabricated from an FDA approved cermet. Because, for the reasons explained *infra,* we cannot understand precisely what is meant by the terminology "fabricated from an FDA approved cermet," we are once again constrained to reverse the examiner's rejection of this claims as being unpatentable over the applied prior art. *See Steele*, 305 F.2d at 862, 134 USPQ at 295 and *Wilson*, 424 F.2d at 1385, 165 USPQ at 496.

New ground of rejection pursuant to 37 CFR § 1.196(b).

Claims 11-18 are rejected under 35 U.S.C. § 112, second paragraph, because the meaning of the term "an FDA approved cermet" appearing in claim 11 is not clear.

The purpose of the second paragraph of Section 112 is to provide those who would endeavor, in future enterprise, to approach the area circumscribed by the claims of a patent, with adequate notice demanded by due process of law, so that they may more readily and accurately determine the boundaries of protection involved and evaluate the possibility of infringement

and dominance. *In re Hammack*, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970). If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. § 112, second paragraph, is appropriate. *In re Venezia*, 530 F.2d 956, 958, 189 USPQ 149, 151 (CCPA 1976).

In the present case, while claims 11-18 require that the implant be fabricated from an FDA approved cermet, the underlying specification offers no guidance whatsoever as to precisely what constitutes an FDA approved cermet. While it might perhaps be possible to consult a list compiled by the United States Food and Drug Administration, if such a listing exists, as to what cermets are or are not approved for use as an implant material at any given time, it is reasonable to assume that said list would be subject to change over time, as when approval is granted (or withdrawn) upon further consideration by the FDA. Furthermore, while it may be argued that the terminology in question is with reference to those cermets that appear on an FDA approved list as of a particular date,[5] there is no indication in the record before us of what that date may be. In light of these

[5]For example, the filing date of the application.

circumstances, we consider that the meaning of the terminology an "FDA approved cermet" appearing in claim 11 would be, at best, difficult to determine with a reasonable degree of certainty, thereby making it appropriate to reject claims 11-18 under 35 U.S.C. § 112, second paragraph.[6]

SUMMARY

The rejection of claims 11-18, under 35 U.S.C. § 112, first paragraph, is affirmed.

The rejection of claims 8, 36 and 38, under 35 U.S.C. § 112, second paragraph, is reversed.

The rejection of claims 1-9, 11-17 and 35-37, as being anticipated by Holt or, in the alternative, as being obvious in view of Holt is affirmed with respect to claims 1-9 and 35-37, but is reversed with respect to claims 11-17 on procedural grounds.

[6]Moreover, because appellant's specification does not state what cermets are FDA approved, thereby making it necessary to go outside the specification to determine the scope of claims 11-18, the terminology "fabricated from an FDA approved cermet" appears to be a incorporation by reference of "essential material" that does not comply with the guidelines set forth in the *Manual of Patent Examining Procedure* § 608.01(p).

The rejection of claims 10, 18, 37 and 38 as being unpatentable over Holt in view of Hirayama is affirmed with respect to claims 10, 37 and 38, but is reversed with respect to claim 18 on procedural grounds.

A new rejection of claims 11-18 pursuant to 37 CFR § 1.196(b) has been made.

Because at least one rejection of each of the appealed claims has been affirmed, the decision of the examiner finally rejecting the appealed claims is affirmed.

In addition to affirming the examiner's rejection of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides that "[a] new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 CFR § 1.197(b) provides:

> (b) Appellant may file a single request for rehearing within two months from the date of the original decision . . . .

37 CFR § 1.196(b) also provides that the appellant, *WITHIN TWO MONTHS FROM THE DATE OF THE DECISION*, must exercise one of

the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner . . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record . . . .

Should the appellant elect to prosecute further before the Primary Examiner pursuant to 37 CFR § 1.196(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED; 37 CFR § 1.196(b)

IRWIN CHARLES COHEN Administrative Patent Judge	)	
LAWRENCE J. STAAB Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
JOHN P. McQUADE Administrative Patent Judge	)	

LJS:hh

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